Remarks

Claims 1-11 are currently pending and stand rejected. Claims 1-9 have been amended, and new claim 12 has been added. Support for new claim 12 can be found at ¶¶ [0031]-[0032] of the Application. No new matter is added by way of this amendment.

Claim Rejection under 35 U.S.C. §102

The Examiner has rejected claims 1 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,011,067 to Hersh. Applicant respectfully disagrees for the following reasons.

Claim 1. as amended herein, recites a topical composition containing from 16% to 70% by weight reduced glutathione, the limitation of original claim 2, now canceled. As confirmed by the Examiner at page 3 of the Office Action, Hersh fails to disclose glutathione in the ranges of 16-70% by weight as is required by claim 1 as now presently amended. Hence, Hersh does not anticipate independent claim 1, and its dependent claims 3-12, and the Examiner's §102(a) rejection has been overcome.

Claim Rejection under 35 U.S.C. §103

The Examiner has rejected claims 1 under 35 U.S.C. §103(b) as being unpatentable over Hersh in view of U.S. Patent No. 5,728,735 to Ulrich. Applicant respectfully disagrees for the following reasons.

The Examiner states that Hersh teaches a method for the treatment of psoriasis including applying a topical composition containing an effective amount of reduced glutathione, and cites examples 1-3 of Hersh. Applicant respectfully disagrees. Hersh does not disclose use of compositions containing glutathione as required by all pending

claims, but rather, Hersh explicitly teaches a composition requiring the "combination of L-glutathione and selenium." (Hersh, col. 6, lines 57-62.) The synergistic combination of glutathione and selenium is required in all embodiments of Hersh, as shown in its examples 1-3 referenced by the Examiner. Hersh discloses that to achieve treatment of psoriasis and related diseases, glutathione and selenium must act synergistically as they are constituents of the same enzymatic system. (*Id.* at col. 7, line 66 to col. 8, line 1.) One of skill in the art would be familiar with the fact that selenium is a part of the enzyme glutathione peroxidase, which metabolizes hydroperoxides formed from polyunsaturated fatty acids. Thus, the disclosure in Hersh would not teach or suggest to one of skill in the art to use glutathione alone as the active ingredient. Moreover, Hersh by requiring synergism of glutathione and selenium, in fact, teaches away from the use of glutathione alone.

Further, all claims, as amended herein, recite compositions containing glutathione in amounts from 16% to 70% by weight in methods for treating psoriasis. In contrast, Hersh explicitly discloses glutathione in amounts from 0.001-15% at col.8, lines 18-19 in its synergistic glutathione-selenium composition. Thus, the disclosure in Hersh would not teach or suggest to one of skill in the art to use glutathione alone in amounts from from 16% to 70% by weight as the active ingredient in compositions employed in methods of treating psoriasis. Moreover, Hersh in disclosing glutathione in amounts from 0.001-15% teaches away from compositions employed in methods of treating psoriasis according to the present invention, i.e. compositions containing glutathione in amounts from 16-70% by weight .

Hence, Hersh alone cannot render obvious the pending claims, all of which require a composition containing the sole active ingredient of glutathione, in amounts of 16-70%. For at least this reason, all pending claims, claims 1 and 3-12 are patentable and nonobvious over Hersh.

In addition to confirming that Hersh does not teach the claimed ranged of glutathione, the Examiner also confirms that it is silent as to alpha-lipoic acid (as recited in claims 11-12). Thus, the Examiner cites Ulrich for teaching alpha-lipoic acid as an active ingredient in topical compositions used in methods for treating psoriasis. (Office Action p.4.) Applicant respectfully disagrees for the following reasons.

There is no suggestion or motivation to combine Hersh and Ulrich, and even if such combination were made, it would not result in the present claims. With respect to Hersh, other than the two synergistic ingredients, required as enzymatic system constituents, i.e. glutathione and selenium, Hersh makes no disclosure as to alpha-lipoic acid and only discloses the additional *optional* ingredients of: superoxide dismutase (*id.* at col. 8, lines 22-45); vitamins, particularly vitamin E and vitamin C (*id.* at col. 8, line 46 to col. 9, line 67); zinc (*id.* at col. 10, lines 1-40); steroid preparations (*id.* at col. 10, lines 48-49); salicylates (*id.* at col. 10, line 53); and antibacterial, fungistatic and fungicidal agents (*id.* at col. 10, lines 55-56). Nowhere in Hersh is there mention of alpha-lipoic acid, as confirmed by the Examiner, nor is there suggestion to venture off this specific list provided by Hersh of optional ingredients to somehow arrive at the addition of alpha lipoic acid.

Likewise, Ulrich has no teaching of combining its active ingredient lipoic acid with anything else, nevermind glutathione-selenium topical compositions to treat psoriasis as disclosed by Ulrich. In fact, Ulrich is directed to composition for combating pain (analgesics) and underlying inflammation and also discusses anti-viral activity (growth-inhibiting activity) thorugh use of <u>oral</u> and <u>parenteral</u>, among others, lipoic acid formulations. (Ulrich at col. 1, lines 47-50; col. 2, line 51-55; col. 3, lines 36-46.) In addition to its lipoic acid primary ingredient, Ulrich lists various auxiliary substances in columns 8-10, including an <u>explicit</u> list of antioxidants at col. 10, lines 32-46. The antioxidant glutathione is <u>absent</u> therefrom. One of skill in the art would <u>not</u> be taught by the disclosure in either Hersh or Ulrich, nor in reading them in combination, to

combine the glutathione disclosed in a synergistic combination with selenium in methods of treating psoriasis with lipoic acid disclosed in Ulrich's analgesic compositions whose primary ingredient is lipoic acid and who discloses auxiliary use of antioxidants other than glutathione. Thus, it is merely hindsight to piece together elements from each reference to arrive at the present claims.

Hence, there is no suggestion in either Hersh or Ulrich to remove one ingredient from Hersh's synergistic topical combination, namely glutathione, and incorporate therein lipoic acid (as disclosed as the primary ingredient in various analgesic formulations, in oral and parenteral forms, among others (Ulrich at col. 3, lines 36-46)) to arrive at topical compositions for treatment of psoriasis containing 16-70% glutathione and the adjunct ingredient of lipoic acid as required by claims 11-12, and specifically lipoic acid in amounts of 0.5-5% by weight as required by claim 12. For at least the aforementioned reasons, the present claims are nonobvious in over Hersh in view of Ulrich.

Conclusion

Applicant respectfully asserts that the Examiner's rejections have been traversed by the aforementioned amendment and remarks. It is respectfully submitted that all of the pending claims are in order for allowance and early notice to that effect is respectfully requested.

Respectfully submitted,

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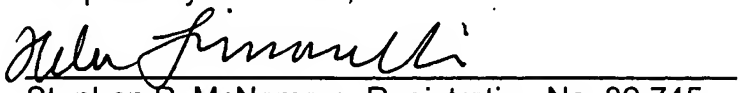

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